

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Previously Presented) An in-line screening capture device for in-line screening of blood collected from a donor using a collection needle connected by a collection duct to a collection bag, comprising:

an inlet for blood collected from the collection needle;

a biochip unit that captures target agents or molecules from the blood; and

an outlet that drains the blood from the in-line screening capture device to the collection duct,

wherein chambers of the in-line screening capture device through which the blood flows have a cross-sectional area that is no smaller than that of the collection duct.

2. (Previously Presented) The in-line screening capture device according to claim 1, wherein the inlet of the in-line screening capture device is directly connected to a rear end of the collection needle.

3. (Currently amended) The in-line screening capture device according to claim 1, wherein the inlet of the in-line screening capture device is connected, ~~via a collection duct,~~ proximate directly to the collection needle.

4. (Currently amended) The in-line screening capture device according to claim 3, wherein the inlet of the in-line screening capture device is connected, ~~via a collection duct,~~ proximate directly to the collection needle so that the temperature of the blood in the in-line screening capture device is approximately 37° degree C.

5. (Previously Presented) The in-line screening capture device according to claim 1, wherein the biochip unit comprises a first biochip and a second biochip that are sequentially arranged between the inlet and the outlet.

6. (Previously Presented) The in-line screening capture device according to claim 5, wherein the first biochip and second biochip are arranged in a parallel stacked fashion.

7. (Previously Presented) The in-line screening capture device according to claim 1, wherein the dimensions of the in-line screening capture device are such that a flow rate of blood flowing through the in-line screening capture device is equal to the flow rate of the collected blood in the absence of the in-line screening capture device.

8. (Previously Presented) The in-line screening capture device according to claim 1, wherein the dimensions of the in-line screening capture device are such that the flow rate of blood flowing through the in-line screening capture device is about 450 ml per 10 minutes.

9. (Previously Presented) The in-line screening capture device according to claim 1, wherein the dimensions of the inlet, the outlet, a surface area of biochips in the biochip unit, and the in-line screening capture device case are such that the collected blood maintains a constant flow rate through the in-line screening capture device.

10. (Previously Presented) The in-line screening capture device according to claim 1, wherein the target agent or molecule comprises at least one protein, nucleic acid molecule or fragment thereof indicative of or specific for a disease in a subject or an infectious agent.

11. (Previously Presented) The in-line screening capture device according to claim 10, wherein the protein is an antibody or an antigen.

12. (Previously Presented) The in-line screening capture device according to claim 5, wherein the first biochip is a nucleic acid amplification technique (NAT) biochip designed to run multiple tests on the first chip.

13. (Previously Presented) The in-line screening capture device according to claim 12, wherein the first biochip captures at least one infectious organism or cell containing a targeted nucleic acid molecule.

14. (Previously Presented) The in-line screening capture device according to claim 13, wherein the infectious organism is a virus, bacteria, fungi, protozoan, mycoplasma or prion and said cell is a cell from the donor of the blood sample.

15. (Previously Presented) The in-line screening capture device according to claim 5, wherein the second biochip is an immunoassay chip designed to run multiple assays on the second biochip.

16. (Previously Presented) The in-line screening capture device according to claim 15, wherein the second biochip captures targeted antigens or antibodies or a combination of targeted antigens and antibodies.

17. (Previously Presented) The in-line screening capture device according to claim 5, wherein the first and second biochips are low density biochips.

18. (Currently amended) ~~The in-line screening capture device according to claim 5;~~  
An in-line screening capture device for in-line screening of blood collected from a donor using a collection needle connected by a collection duct to a collection bag, comprising:

an inlet for blood collected from the collection needle;

a biochip unit that captures target agents or molecules from the blood; and

an outlet that drains the blood from the in-line screening capture device to the collection duct,

wherein chambers of the in-line screening capture device through which the blood flows have a cross-sectional area that is no smaller than that of the collection duct,

wherein the biochip unit comprises a first biochip and a second biochip that are sequentially arranged between the inlet and the outlet, and

wherein the first and second biochips comprise microarrays in which the analytes that bind to the target agent or molecule, if present in the blood, are arranged along the length of the biochips in the direction of blood flow over the first and second biochips, respectively.

19. (Previously Presented) The in-line screening capture device according to claim 16, wherein the first and second biochips comprise covalently attached analytes.

20. (Previously Presented) The in-line screening capture device according to claim 1, wherein the outlet includes a funnel and a filter.

21. (Previously Presented) The in-line screening capture device according to claim 1, further comprising an anti-backflow device that prevents the blood from flowing back towards the inlet.

22. (Previously Presented) The in-line screening capture device according to claim 1, wherein the inlet and outlet are capable of being sealed when the screening capture device is removed from the collection needle and the collection duct.

23. (Previously Presented) The in-line screening capture device according to claim 5, wherein the in-line screening capture device comprises a lid that can be robotically removed to facilitate robotic removal of the first biochip and the second biochip.

24. (Previously Presented) An in-line screening system for in-line screening of blood collected from a donor using a collection needle connected by a collection duct to a collection bag, comprising:

an in-line screening capture device comprising:

an inlet for blood collected from the collection needle;

a biochip unit that captures target agents or molecules from the blood; and

an outlet that drains the blood from the in-line screening capture device to the collection duct,

wherein chambers of the in-line screening capture device through which the blood flows have a cross-sectional area that is no smaller than that of the collection duct; and

at least one biochip processor for detecting at least one captured target agent or molecule.

25. (Previously Presented) The in-line screening system of claim 24, wherein said biochip processor is capable of amplifying said target agent or molecule.

26. (Previously Presented) The in-line screening system according to claim 24, wherein the biochip processor is a sealed disposable unit having a nucleic acid amplification technique (NAT) portion for processing a first biochip and an immunoassay portion for processing a second biochip.

27. (Previously Presented) The in-line screening system according to claim 26, wherein said target molecule is a nucleic acid molecule and the NAT portion comprises:

a biochip holder;

at least one reservoir for holding a sample;

at least one amplification reaction chamber connected to the reservoir; and

at least one detection component connected to the amplification reaction chamber.

28. (Previously Presented) The in-line screening system according to claim 27, wherein the NAT portion further comprises:

at least one reagent container connected to the reservoir; and

at least one reagent container connected to the reaction chamber.

29. (Previously Presented) The in-line screening system according to claim 28, wherein the NAT portion further comprises the first biochip held in the biochip holder.

30. (Previously Presented) The in-line screening system according to claim 29, wherein the first biochip is held such that a surface containing analytes is in contact with at least one elution and lysing buffer.

31. (Previously Presented) The in-line screening system according to claim 28, wherein the detection component is at least one microfluidity chamber.

32. (Previously Presented) The in-line screening system according to claim 24, comprising more than one biochip processor.

33. (Previously Presented) The in-line screening system according to claim 26, wherein the target molecule is a target antibody or a target antigen and the immunoassay portion comprises:

a biochip holder;

at least one reservoir for holding a sample;

at least one reaction chamber connected to the reservoir; and

at least one detection component connected to the reaction chamber.

34. (Previously Presented) The in-line screening system according to claim 33, wherein the immunoassay portion further comprises:

at least one reagent container connected to the reservoir; and

at least one reagent container connected to the reaction chamber.

35. (Previously Presented) The in-line screening system according to claim 34, wherein the immunoassay portion further comprises the second biochip held in the biochip holder, and wherein the second biochip is covalently attached to analytes that bind to the target antibody or the target antigen.

36. (Previously Presented) The in-line screening system according to claim 35, wherein the second biochip is held such that the attached analytes are in contact with at least one buffer.

37. (Previously Presented) The in-line screening system according to claim 33, wherein the detection component is at least one microfluidity chamber.

38. (Previously Presented) The in-line screening system according to claim 33, comprising at least two reaction chambers, one for the detection of a target antibody and one for the detection of a target antigen.

39. (Previously Presented) The in-line screening system according to claim 38, wherein each reaction chamber is connected to at least one detection component comprising is at least one microfluidity chamber.

40. (Withdrawn) A method of in-line screening of blood collected from a donor using a collection needle connected by a collection duct to a collection bag, comprising:

providing a screening capture device comprising: an inlet for blood collected from the collection needle, a biochip unit that captures a target agent or molecule from the blood, and an outlet that drains the blood from the screening capture device to the collection duct;

inserting the screening capture device between the collection needle and the collection duct proximate to the collection needle so that blood flowing through the screening capture device is approximately at a human body temperature; and

allowing blood to flow through said screening capture device.

41. (Withdrawn) The method of claim 40, further comprising the step of removing the screening capture device for further processing of the biochip unit.

42. (Withdrawn) The method according to claim 40, further comprising:  
robotically opening the screening capture device to remove the biochip unit; and

inserting the biochip unit into a biochip processor for processing of biochips in the biochip unit.

43. (Withdrawn) The method according to claim 42, wherein the biochip processor comprises a nucleic acid amplification technique (NAT) portion for processing a first biochip and an immunoassay portion for processing a second biochip.

44. (Withdrawn) The method according to claim 43, wherein said target molecule is a nucleic acid molecule and the NAT portion comprises:

a biochip holder comprising a first biochip;



- at least one reservoir for holding a sample eluted from the first biochip;
- at least one amplification reaction chamber connected to the reservoir; and
- at least one detection component connected to the amplification reaction chamber.

45. (Withdrawn/Previously Amended) The method according to claim 44, wherein the NAT portion further comprises: at least one reagent container connected to the reservoir, wherein said method further comprises contacting the first biochip with at least one buffer from the reagent container that elutes and lyses the captured target agent or molecule from the first biochip to form a solution that collects in the reservoir.

46. (Withdrawn) The method according to claim 45, further comprising:

- pumping the solution in the reservoir to the at least one amplification reaction chamber;
- providing at least one additional reagent container that contains nucleic acid amplification reagents and allowing the reagents to flow into the amplification reaction chamber containing the solution;
- providing sufficient conditions to amplify at least one nucleic acid molecule in the solution; and
- detecting the presence of the amplified nucleic acid molecule in the detection component.

47. (Withdrawn) The method according to claim 46, wherein the detection component is at least one microfluidity chamber and detecting the presence of the amplified nucleic acid molecule by a nucleic acid hybridization method and the detection of a signal.

48. (Withdrawn) The method according to claim 42, further comprising utilizing more than one biochip processors in parallel.

49. (Withdrawn) The method according to claim 43, wherein said target molecule is an antibody or an antigen and the immunoassay portion comprises:

- a biochip holder comprising a second biochip;
- at least one reservoir for holding a sample eluted from the first biochip;
- at least one reaction chamber connected to the reservoir; and
- at least one detection component connected to the reaction chamber.

50. (Withdrawn/Previously Amended) The method according to claim 49, wherein the immunoassay portion further comprises: at least one reagent container connected to the reservoir, wherein said method further comprises contacting the second biochip with at least one buffer from the reagent container that elutes the captured target molecule from the second biochip to form a solution that collects in the reservoir.

51. (Withdrawn) The method according to claim 50, further comprising:
- pumping the solution in the reservoir into the at least one reaction chamber;
  - providing at least one additional reagent container that contains a reagent comprising an antigen linked to a signal amplification system or an antibody linked to a signal amplification system and allowing the reagent to flow into the reaction chamber containing the solution;
  - providing sufficient conditions to allow binding of the reagent to a target antibody or antigen in the solution; and
  - detecting the presence of the target antibody or antigen in the detection component.

52. (Withdrawn) The method according to claim 51, wherein the detection component is at least one microfluidity chamber and detecting the presence of the signal by binding to an antibody immobilized on the wall of the chamber.

53. (Withdrawn) The method according to claim 49, further comprising utilizing more than one biochip processors in parallel.

54. (Withdrawn) The method according to claim 49, comprising at least two reactions chambers, one for the detection of a target antibody and one for the detection of a target antigen.

55. (Withdrawn) The method according to claim 54, wherein each reaction chamber is connected to at least one detection component comprising is at least one microfluidity chamber.